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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,977	03/22/2004	Matthew Oliver Fraser	046562/274660	1508

826 7590 01/22/2007

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EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/805,977	FRASER ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *67-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *67-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/15/06 10/1/04 11/6/06 4/6/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 67-88 are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 72 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. In particular, Applicant has not provided a description of how to arrive at a ratio of active agents based on "a fraction of their respective ED50 values." The phrase "a fraction" is unclear since it is unknown what the fraction is. Further, how does one determine the ED50 values as they related to therapeutic efficacy as claimed?

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also

arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 67-71, 73-80, 84 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6974818 to Kyle et al. alone and in view of US Patent No. 6967210 to Smith et al.

Kyle et al. teach a method of treating UI and bladder detrusor muscle instability comprising oxybutynin (see col 1 lines 40-45 and 64). The therapeutic efficacy taught is due to physiologic bladder contractions which result in large part from acetylcholine-induced stimulation of post-ganglionic muscarinic-receptor sites on bladder smooth muscle (see col1 lines 55-60) which are generally treatable with drugs having bladder relaxant properties such as oxybutynin. Kyle et al. further define urinary incontinence to include uncontrollable urination, generally caused by bladder detrusor muscle instability (see col 1 lines 40-45) which is interpreted by the Examiner to include urinary frequency, urinary frequency and nocturia. Kyle et al. further teach examples of useful therapeutic agents for treating or preventing UI include, but are not limited to.... oxybutynin, (see col 45 lines 65-end). Kyle et al. further teach a composition comprising gabapentin (see col 6 lines 55-56) or pregabalin (see col 42 line 39).

Kyle et al. teach that the composition can be administered together with other active agents and via oral, rectal etc. routes (see col 36 lines 10-15) wherein the formulations comprise those suited for oral delivery (see col 37 lines 45-50) and that the precise administration is dependent upon the seriousness of the condition being treated and should be decided according to the judgment of the practitioner and each patient's circumstances (see col 39 lines 20-30) and further that the active agents can be administered prior to or subsequent to other active agents (see col 47 lines 65-end). To

that end, the amounts of active agents are administered based on a patients needs and sensitivities as well as pursuant to safe dosing schedules which are further taught as efficacious for the treatment of urinary incontinence.

Although Kyle et al. teach and/or suggest each limitation of the above claims, the rejection is further bolstered by Smith et al. Smith et al. teach a combination treatment for bladder irritation (see col 4 lines 30-35) wherein bladder irritation includes overactivity of the detrusor muscle (see col 7 lines 50-61) comprising gabapentin (see col 19 Example 9).

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary skill in the art would have been motivated to combine the references because both are directed to the treatment of overactive detrusor muscle. Further, Kyle et al. and Smith et al. both teach a combination therapy for the treatment of pain and to that end Kyle et al. teaches a combination therapy comprising both gabapentin and oxybutynin. The teaching of Smith et al. that gabapentin is efficacious for the treatment of overactive detrusor muscle in combination with the combination therapy of Kyle et al. and make prima facie obvious how to use the claimed invention at the time that it was made.

Claims 67-82, 84-86 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6974818 to Kyle et al. as applied to claims 67-71, 73-80, 84 and 88 above in view of US Patent Application Publication No. 20040242617 to Christoph.

Christoph teaches that muscarinic antagonists such as oxybutynin, propiverine and tolterodine are efficacious in the treatment of urinary incontinence (i.e. detrusor muscle instability) (see paragraphs 0003, 0006 and 0082-0083) which includes the urge to urinate as well as increased frequency of urination (see paragraph 0003).

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary skill in the art would have been motivated to combine the references because both are directed to the treatment of urinary incontinence based upon detrusor muscle instability. Further, Kyle et al. teach a combination comprising gabapentin and oxybutynin wherein Christoph provides a suggestion to combine gabapentin (or pregabalin) with oxybutynin for example since Christoph teaches the efficacy of the muscarinic antagonists for the same indication. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Claims 83 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6974818 to Kyle et al. as applied to claims 67-71, 73-80, 84 and 88 above in view of US Patent No. 6017927 to Takeuchi et al.

Takeuchi et al. teach that muscarinic antagonists such as solifenacin hydrochloride (the compound of formula Ia) is efficacious in treating urinary diseases such as unstable bladder and nocturnal enuresis (see col 3 lines 60-66 and col 4 lines 10-20).

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary skill in the art would have been motivated to combine the references because both are directed to the treatment of urinary incontinence and uncontrollable bladder. Further, Kyle et al. teach a combination comprising gabapentin and oxybutynin wherein Takeuchi et al. provide a suggestion to treat urinary incontinence with a combination therapy comprising solifenacin hydrochloride. Since Takeuchi et al. teach the efficacy of the muscarinic antagonist for the same indication as Kyle et al. one of ordinary skill in the art would be further motivated to combine the references. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 67-88 are provisionally rejected on the ground of nonstatutory double patenting over claims 22-38 of copending Application No. 10/549029. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully claimed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a pharmaceutical composition comprising an α2δ subunit calcium channel modulator (i.e. gabapentin) and an antimuscarinic (i.e. Oxybutynin).

Claims 67-88 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-5 of copending Application No. 11/400666. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully claimed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a pharmaceutical composition comprising an α2δ subunit calcium channel modulator and tolterodine.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9 January 2007
MG

Ardin H. Marschel 1/13/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER